

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

IN RE NATIONAL PRESCRIPTION
OPIATE LITIGATION

This document relates to:

The County of Summit, Ohio, et al.
v.
Purdue Pharma L.P., et al.
Case No. 18-op-45090

MDL NO. 2804

Case No. 17-md-2804

Hon. Dan Aaron Polster

**THE MANUFACTURER DEFENDANTS' OBJECTIONS TO THE
REPORT AND RECOMMENDATION ON THEIR JOINT
MOTION TO DISMISS PLAINTIFFS' SECOND AMENDED COMPLAINT**

The Report and Recommendation (“R&R”)¹ repeatedly acknowledges serious and dispositive flaws in Plaintiffs’ claims, but nonetheless permits those claims to proceed, on a theory that perhaps Plaintiffs will be able to remedy the flaws through discovery. But the Supreme Court has done away with the notion that pleadings are sufficient whenever there is a mere possibility that the plaintiff might discover some set of facts to support recovery. In any event, Plaintiffs’ claims fail as a matter of law, for multiple reasons, and no amount of discovery would remedy the fundamental problems with their case. In permitting virtually all of Plaintiffs’ claims to proceed, the R&R disregards clear law that each claim in a complaint must be legally cognizable and adequately pleaded, and ignores the enormous benefit to the Court and all parties that would result from an appropriate narrowing of the claims, both on the scope of discovery in this massive litigation and the potential for successful settlement negotiations.²

Nowhere is this truer than with Plaintiffs’ RICO claims. The R&R ignores clear Sixth Circuit precedent that derivative claims such as those alleged here – that is, claims for economic losses flowing from alleged personal injuries to third parties – do not confer RICO standing. *See Perry v. American Tobacco Co.*, 324 F.3d 845 (6th Cir. 2003). The rationale in *Perry* applies with even greater force here, where Plaintiffs seek recovery not only for costs of treating addicted citizens, but also for injuries even more remote and attenuated from the alleged misconduct, such as lost revenue from property taxes in communities affected by opioid abuse.

¹ The Manufacturer Defendants object to the entirety of the R&R, save for the decisions to dismiss the common law public nuisance claim and the City of Akron’s statutory nuisance claim (R&R at 60, 70). However, for sake of brevity, Defendants address here only those errors in the R&R having greatest impact on the outcome of these motions, while preserving other objections and the right to re-raise them later in the litigation. Further, Defendant Noramco, Inc. was not referenced as one of the “Manufacturers” that joined in the Motion to Dismiss, R&R at 1 n.3, despite having joined the Motion “to the extent applicable,” 499-1, #7656 n.2. Noramco thus requests clarification that Noramco is included in the moving Manufacturer Defendants and is entitled to all applicable relief.

² In complex litigation, a court should take an active role in “identifying, clarifying, and narrowing pivotal factual and legal issues as soon as practicable.” Manual Complex Lit. § 30.1 (4th ed.). Doing so will “limit the scope and volume of discovery, reduce cost and delay, facilitate the prospects of settlement, and improve the trial.” *Id.*

Similarly, the R&R fails to meaningfully consider the ways in which federal and state law circumscribe Plaintiffs' other claims, largely ignoring key points concerning application of the statute of limitations and the lack of a duty to monitor for and report suspicious orders of controlled substances by parties who place orders *not* with manufacturers but with downstream distributors or pharmacies. The Court should revisit these issues and properly narrow the sweep of this unprecedented litigation.

ARGUMENT

I. PLAINTIFFS LACK STANDING TO SUE UNDER RICO

The R&R errs in suggesting that discovery might solve a fundamental problem with Plaintiffs' RICO claims: lack of standing. This puts the cart before the horse. Standing is a "threshold question involving . . . statutory limitations on who may sue, regardless of the merits of that person's claim." *Trollinger v. Tyson Foods, Inc.*, 370 F.3d 602, 612 (6th Cir. 2004). The Sixth Circuit has recognized that a RICO plaintiff has standing only if he has been "*injured in his business or property by reason of*" conduct constituting a RICO violation. *Id.* (emphasis added). It is clear from the Complaint that Plaintiffs lack standing to pursue RICO claims, and no amount of discovery will change that conclusion. Those claims must be dismissed now. *See NicSand, Inc. v. 3M Co.*, 507 F.3d 442, 449–50 (6th Cir. 2007) (cases lacking statutory standing should be dismissed before discovery).³

A. Plaintiffs' Injuries Are Derivative, Not Direct

The R&R misconstrues the claims here as asserting "direct" injuries, rather than

³ Dismissal of the federal RICO claims would not divest this Court of jurisdiction. *See* 28 U.S.C. § 1367(c)(3) (granting district courts discretion to entertain supplemental state law claims when federal claims are dismissed); *Varsity Brands, Inc. v. Star Athletica, LLC*, 799 F.3d 468, 493 (6th Cir. 2015) (courts are not obligated to dismiss supplemental state-law claims after dismissal of all federal claims); *Orton v. Johnny's Lunch Franchise, LLC*, 668 F.3d 843, 850 (6th Cir. 2012) ("[S]upplemental jurisdiction does not disappear" when federal claims are dismissed).

derivative harm. The allegation that Plaintiffs have been “impacted by the opioid epidemic” (R&R at 27) is not sufficient to state a direct injury.⁴

Instead, both the Supreme Court and the Sixth Circuit have held that standing depends on the relationship between the plaintiff and the defendant: only a “direct” and “immediate” victim of the misconduct may sue, while those who suffer only “derivative or passed-on injuries” lack RICO standing. *See Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 460 (2006); *Trollinger*, 370 F.3d at 614. The R&R acknowledges this, but then incorrectly suggests that whether an injury is “direct” for purposes of standing is wholly subsumed by the proximate cause inquiry (R&R at 13 n. 11). That is wrong. The word “direct” is used in two different contexts in the required analysis and has two distinct meanings. For standing to exist, an injury must be “direct” in the sense of being both (1) non-derivative of some third party’s injury (*the standing analysis*), *see Trollinger*, 370 F.3d at 614; and (2) having an uninterrupted, direct, and not overly attenuated causal chain from conduct to injury (*the proximate cause analysis*), *see Anza*, 547 U.S. at 457.

Although these two concepts overlap to some extent, they are distinct requirements, which the Sixth Circuit has expressly charged courts with analyzing separately. *Trollinger*, 370 F.3d at 613, 615 (“The point of all this is not just that the distinction between statutory standing and proximate causation exists, but that unbundling these distinct concepts has practical significance for RICO cases. . . .”). The R&R, however, fails to appreciate the distinction between directness in the context of standing and directness in the context of proximate cause, and thus erroneously conflates the analyses by assuming that satisfying the legal requirements of

⁴ Numerous cases reveal that “impact” alone is not sufficient to state a RICO claim. For instance, in *Hemi Goup, LLC v. City of New York*, 559 U.S. 1, 4–6 (2010), there was no dispute that the city lost tax revenue as a result of defendants’ failure to provide information about customers’ purchases that could have been taxed. In *City of Cleveland v. Ameriquest Mort. Securities, Inc.*, 615 F.3d 496, 503 (6th Cir. 2010), the city’s finances were adversely impacted by the mortgage foreclosure crisis allegedly created by the defendants’ actions. But in both of those cases, the alleged injury was not sufficient to state a viable claim. *See Hemi*, 559 U.S. at 18; *Ameriquest*, 615 F.3d at 506.

proximate cause necessarily confers RICO standing (*see* R&R at 13 n.11).

Plaintiffs' claimed injuries cannot be deemed direct, logically or legally. A claim with a "derivative-injury problem" can and should be dismissed on the pleadings and "a court often finds no need to look beyond the face of the complaint in order to determine that the plaintiff lacks standing because the injury was passed on by another party that had a more direct relationship with the defendant." *Trollinger*, 370 F.3d at 615. That is precisely the case here. The R&R summarizes Plaintiffs' injuries as falling into three categories: "(1) public expenditures made in direct response to opioid use and trafficking; (2) lost tax revenue resulting from abuse, misuse, and addiction; and (3) losses caused by diminished property values" (R&R at 13). Each of these claimed injuries is necessarily derivative of harms to individual opioid users: it is the opioid user who (if anyone) was directly harmed, and it is only as a result of this harm – in the aggregate – that Plaintiffs can claim to have experienced additional public expenditures, lost tax revenue, and diminished property values.⁵ Plaintiffs thus lack RICO standing for these claims.

The distinction between a derivative and a non-derivative injury is well illustrated by the Sixth Circuit's controlling decision in *Perry v. American Tobacco Co.*, 324 F.3d 845 (6th Cir. 2003) – the closest case on point in this Circuit but one not cited anywhere in the R&R. Plaintiffs there were individual insurance plan subscribers who alleged that because of the tobacco manufacturers' conduct, they paid increased premiums to account for medical care provided to smokers in the same insurance pool. *Id.* at 847. The Sixth Circuit affirmed a Rule 12(b)(6) dismissal, and concluded that plaintiffs lacked RICO standing because their claims were

⁵ The R&R also suggests that it was somehow *Defendants'* fault for not differentiating between categories of damages claimed by Plaintiffs (R&R at 22). But it is Plaintiffs' burden (not Defendants') to plead claims for which they have RICO standing, and all the categories of damages alleged are derivative of harm to opioid users.

“inherently contingent” on injury to third-party smokers, and thus did not meet the requirement for direct (in the sense of non-derivative) injury. *Id.* at 848–49.⁶ Any harm suffered by individual smokers would be a direct injury, but increased health care costs incurred by third-party payors, or resulting premium increases to subscribers, would not. *See id.* So too here. Because standing for RICO claims is limited to those directly harmed by the alleged conduct, it does not extend to Plaintiffs, who assert only harm derivative of that initial injury.

B. Plaintiffs’ Claimed Injuries Are Not to “Business or Property”

1. Plaintiffs’ damages all flow from residents’ personal injuries

The R&R correctly recognizes that RICO standing requires an injury to “business or property” (R&R at 13), and that pecuniary losses resulting from personal injury are thus barred (R&R at 22–23). Because personal injury is not an injury to “business or property,” any resulting monetary damage is not a “proprietary type of damage” sufficient to grant RICO standing. *Jackson v. Sedgwick Claims Mgmt. Svcs.*, 731 F.3d 556, 562 n.2, 564–65 (6th Cir. 2013) (*en banc*). As the Sixth Circuit clearly stated in *Jackson*, “both personal injuries and pecuniary losses flowing from those personal injuries fail to confer relief” under RICO. *Id.* at 565. The R&R recognizes this as a “crucial question in this litigation” and then notes the obvious: Plaintiffs’ “injuries *plainly stem* from opioid use/abuse and *not some other possible source*” (R&R at 23, 27) (emphasis added).

Although these principles articulated in *Jackson* require dismissal of the claims that flow from personal injuries, the R&R suggests discovery is needed to determine *which* claims flowed

⁶ As discussed further below, the *Perry* court also found that the claimed injuries, because of their derivative nature, failed RICO’s proximate cause requirement on remoteness grounds. *Id.* at 849–50.

from alleged personal injury (R&R at 23–24).⁷ That is incorrect. The Complaint on its face reveals that *all* of Plaintiffs’ claims flow from their residents’ alleged personal injuries:

- the costs of treating patients suffering from opioid addiction or disease would not be incurred *unless opioid users suffered personal injury*;
- the expenses associated with additional emergency personnel would not be incurred *unless opioid users suffered personal injury* necessitating emergency medical services;
- there would be no loss of tax revenue *unless opioid users suffered personal injury* rendering them unable to work; and
- property values would not be diminished *unless opioid users suffered personal injury*, resulting in blighted neighborhoods.⁸

At a minimum, the R&R should not have deferred dismissing *any* claims because it is, supposedly, unclear if *some* might flow from personal injuries. On a motion to dismiss, a court should dismiss any claims for which it is clear from “the face of the complaint . . . that the plaintiff lacks standing.” *Trollinger*, 370 F.3d at 615. On multiple occasions, the Sixth Circuit has affirmed that it is appropriate to dismiss RICO claims on a 12(b)(6) motion. *See, e.g., Jackson*, 731 F.3d at 562–63 (affirming 12(b)(6) dismissal for lack of RICO standing); *Perry*, 324 F.3d at 848–49 (affirming 12(b)(6) dismissal for lack of RICO standing or causation).

2. Public expenditures made in a sovereign capacity are not injury to business or property

Finally, the public expenditures for which Plaintiffs seek recovery are not injury to “business or property” because they were made in Plaintiffs’ sovereign – not commercial –

⁷ The R&R so found despite the express acknowledgment that Plaintiffs’ injuries do stem from opioid use/abuse, and cautioning that the R&R should not be construed as an affirmative ruling that all of Plaintiffs’ injuries should in fact survive (R&R at 24 n.18).

⁸ For largely the same reasons, Plaintiffs’ common law negligence claim (Count 7) fails, as the Ohio Product Liability Act abrogates *all* product-related causes of action seeking compensatory damages for personal injury. The R&R acknowledges this point, but just as with the RICO claims, incorrectly concludes that dismissal of Plaintiffs’ claims cannot be allowed without discovery to determine whether “*all* of Plaintiffs’ claimed injuries stem from death, physical injuries, or physical damage to property” (R&R at 60 n.39 (emphasis in original)).

capacities. The R&R acknowledges that the Ninth Circuit in *Canyon Cty. v. Syngenta Seeds, Inc.*, 519 F.3d 969 (9th Cir. 2008), held governmental expenditures like those sought here do not qualify as injuries to “business or property” under RICO (R&R at 15). The R&R speculates that Sixth Circuit would not follow *Canyon County*, even though the Sixth Circuit ***has cited the decision repeatedly*** on various issues (R&R 15–22, 21 n.16). *See e.g., City of Cleveland v. Ameriquest Mort. Sec., Inc.*, 615 F.3d 496, 504 (6th Cir. 2010). Simply put, the R&R’s rejection of *Canyon County* is unsound.

First, the R&R views *Canyon County* as contrary to the Supreme Court’s interpretation of analogous “business or property” language in the Clayton Act. That is not the case. In *Hawaii v. Standard Oil Company of California*, 405 U.S. 251, 264 (1972), the Court held that the Clayton Act’s “business or property” limitation allows a government to recover for damages to its “commercial interests” but ***not*** for damages to its sovereign interests. The R&R acknowledges this express limitation but suggests that it “was greatly softened by *Reiter*” (R&R at 16). But the *Reiter* Court simply held that *Hawaii* used the phrase “commercial interests” “as a generic reference to the interests of the State of Hawaii as ***a party to a commercial transaction.***” *Reiter v. Sonotone Corp.*, 442 U.S. 330, 341–42 (1979) (emphasis added). That is, to recover under the Clayton Act, a government need not be a “business” but must be a “consumer in the marketplace.” *Id.* Obviously, that holding does not stand for the proposition that a government can recover for the cost of public service expenditures and/or lost tax revenue. Indeed, consistent with *Canyon County*, the *Reiter* Court expressly reaffirmed the core principle that a sovereign cannot recover for claims that are derivative of its citizens’ injuries. *Id.* at 342 (referring to the holding in *Hawaii*, “We noted that a ‘large and ultimately indeterminable part of the injury to the “general economy”’ for which the State sued was ‘no more than a reflection of

injuries to the “business or property” of consumers’ for which, on a proper showing, they could recover in their own right.”).

Second, the R&R finds that *Canyon County* conflicts with two Seventh Circuit cases that held RICO’s “business or property” limitation sweeps beyond “commercial interests and competitive injuries” (R&R at 16–17).⁹ But the Seventh Circuit itself has since *expressly rejected* whatever broader reading of RICO standing may be suggested in those two cases. In *Dillon v. Combs*, the court unequivocally held that “‘business or property’ [under RICO]. . . *does not include sovereign or derivative interests.*” 895 F.2d 1175, 1177 (7th Cir. 1990) (emphasis added); *see also People of State of Ill. v. Life of Mid-Am. Ins. Co.*, 805 F.2d 763, 767 (7th Cir. 1986) (not an injury to “business or property” when government sues on behalf of citizens in *parens patriae* capacity).

The decision in *Canyon County* is directly on point here, and the R&R’s prediction that the Sixth Circuit would not follow it is both speculative and unpersuasive. No court has rejected *Canyon County*. The decision provides a thoughtful analysis of the RICO statute and its “business or property” language, and this Court should follow that on-point Circuit decision.

II. THE RICO CLAIMS FAIL FOR LACK OF PROXIMATE CAUSE

Plaintiffs’ claimed losses are also too remote to satisfy RICO’s proximate cause requirement. *See Trollinger*, 370 F.3d at 614 (even if plaintiff and defendant have a “*direct* and not a *derivative* relationship, the causal link . . . may still be too weak to constitute proximate cause” (emphasis in original)). And while proximate cause problems may often be “fodder for a

⁹ Neither of those cases is on point. *Schacht v. Brown*, 711 F.2d 1343, 1357–58 (7th Cir. 1983), does not relate to the “business or property” definition at all, but rather whether only a “competitor” may sue under RICO. In rejecting that “competitive injury” limitation, the court certainly did not hold that a government may recover for sovereign injuries. And *Illinois Dep’t of Revenue v. Phillips*, 771 F.2d 312, 313 (7th Cir. 1985), relates to the specific situation where a government is directly defrauded – there through a scheme involving the “mailing of nine fraudulent tax returns to the Illinois Department of Revenue.”

summary judgment motion,” *Id.* at 615, cases can be, and regularly are, dismissed at the Rule 12 stage for failure to plead proximate cause. *See City of Cleveland*, 615 F.3d at 503 (clarifying *Trollinger* did not mean a motion to dismiss can never be granted on proximate cause, and noting that Supreme Court did so in *Anza*). Here, the R&R assumes that discovery would be necessary to determine whether “Plaintiffs’ injuries are so remote as to bar any potential recovery” (R&R at 27). But the R&R does not explain what additional facts might be learned in discovery that would strengthen – much less shorten – the necessary causal link between conduct and injury. Indeed, at its core, proximate cause is not a fact-based inquiry, it is a policy-based one. The concept of proximate cause is “shorthand for the policy-based judgment that not all factual causes contributing to an injury should be legally cognizable causes.” *CSX Transp., Inc. v. McBride*, 564 U.S. 685, 701 (2011). Instead, because the “consequences of an act go forward to eternity ... courts and legislatures appropriately place limits on the chain of causation that may support recovery on any particular claim.” *Id.*

Plaintiffs’ own allegations make plain that their claimed injuries are simply too remote and attenuated to be saved by discovery. For example, Plaintiffs’ fraudulent marketing theory depends on an alleged chain from conduct to injury as follows: (i) a Manufacturer made deceptive claims in promoting its opioids (***the conduct***); (ii) some physicians were exposed to that Manufacturer’s claims; (iii) which caused some of those physicians to write medically inappropriate opioid prescriptions they would not have otherwise written; (iv) which caused some of their patients to decide to take opioids; (v) which caused some of those individuals to become addicted to opioids; (vi) which caused some of those addicted individuals to need additional medical treatment, to neglect or abuse their families, to lose their jobs, and/or to commit crimes; (vii) which caused Plaintiffs to expend additional resources on emergency

services, and to lose revenue from a decreased working population and/or diminished property values (*the injury*).

That tortured chain of causation reveals – facially, and with no need for discovery – that Plaintiffs’ alleged injuries are far removed from the wrongful conduct alleged and turn on independent intervening acts of doctors, pharmacists, distributors, and (in many instances) criminal actors. Thus, Plaintiffs’ own allegations, accepted as true, establish that their injuries could not have been proximately caused by the Manufacturers’ conduct. The Sixth Circuit, and other federal courts around the country, have repeatedly rejected similar multi-layered and speculative causal theories in cases by governments and health benefit providers as too attenuated and remote to establish RICO proximate causation. *See, e.g., Perry*, 324 F.3d at 849–51 (affirming dismissal of RICO claims against tobacco companies for lack of proximate cause and collecting cases uniformly rejecting claims against tobacco companies for increased healthcare expenses); *City of Cleveland*, 615 F.3d at 499–500 (affirming dismissal of RICO claims asserting harm such as reduced tax revenue and increased public expenditures for fire and police protection flowing from alleged misconduct in financing subprime home mortgages).¹⁰

The R&R’s heavy reliance on *In re Neurontin Marketing & Sales Practices Litigation*, 712 F.3d 21 (1st Cir. 2013), particularly for its proximate cause analysis under RICO, is misplaced (R&R at 35). That case has never been cited by the Sixth Circuit for any proposition, and has been rejected by numerous other Circuit courts. *See, e.g., Sidney Hillman Health Center of Rochester v. Abbott Labs.*, 873 F.3d 574, 578 (7th Cir. 2017) (declining to follow *Neurontin* and noting contrary decisions by the Second, Ninth, and Eleventh Circuits). Moreover, even

¹⁰ In analyzing proximate cause, the R&R relies on the Ohio Supreme Court’s decision in *Cincinnati v. Beretta U.S.A. Corp.*, 768 N.E.2d 1136 (Ohio 2002), rather than the Sixth Circuit’s decision in *Perry*, even while acknowledging that “the facts of this case differ [from those of *Beretta*] in some respects...” (R&R at 80–81). *Perry*, however, is binding here.

though the R&R cited *Neurontin* favorably multiple times across multiple issues, that decision has virtually nothing in common with the case before this Court. In *Neurontin*, Plaintiffs were third-party payors who alleged that (1) the defendants made fraudulent representations about the efficacy of the drug for *off-label purposes*; (2) the representations were made *directly to the third-party payors*, causing them to include the drug in their approved formularies; and (3) as a result, the third-party payors paid more for their members' medical care because Neurontin cost more than the alternative medications that would otherwise have been prescribed. 712 F.3d at 28–32. These facts are simply not presented by the allegations here.¹¹

But rather than dismissing, or at least limiting, Plaintiffs' claims, the R&R waves away any causation problem, suggesting that it is “inescapable in the aggregate” (R&R at 27). This approach, however, merely concedes that many of Plaintiffs' injuries were not causally linked to the alleged misconduct.¹² More fundamentally, any aggregate approach does not obviate the need for but-for and proximate causation. Even the *City of Oakland* case quoted in the R&R makes this clear: “where damages are aggregative, precision is not expected” but “aggregative injury itself does not obviate proximate cause analysis” (R&R at 29 (quoting *City of Oakland*, 2018 WL 3008538, at *1 (N.D. Cal. June 15, 2018))). Thus, with respect to Counts I–IV, the Court must dismiss, or, at a minimum, trim those claimed injuries that are too remote.¹³

¹¹ Moreover, much of the harm Plaintiffs allege cannot even meet the test for ‘but for’ causation. Plaintiffs tacitly acknowledge that only some of the opioid prescriptions for chronic, long-term pain were medically inappropriate (R&R at 27), but then do not even attempt to identify which of those were written as a result of the alleged misconduct. Plaintiffs provide virtually no facts to show their hypothesized “but for” causal chain.

¹² In addition, the R&R errs by refusing to credit Plaintiffs' concessions. Plaintiffs expressly disclaim that they are seeking to hold the Manufacturers liable for simply representing that opioids can be a “safe and effective long-term treatment of chronic, non-cancer pain.” MTD Opp. at 116. If that is so, Plaintiffs should have no objection to this Court entering an order to that effect, thus narrowing the scope of this dispute for discovery and settlement purposes.

¹³ The federal RICO analysis of “applies equally” to claims under Ohio’s Corrupt Practices Act, O.R.C. § 2923.31 *et seq.* *Aaron v. Durrani*, 2014 WL 996471 (S.D. Ohio Mar. 13, 2014); *see also* R&R at 56. Accordingly, the analysis in Sections I and II of this Objection apply with equal force to Counts I–IV. Further, the lack of proximate

III. PLAINTIFFS HAVE NOT SATISFIED THEIR BURDEN OF PLEADING TOLLING TO SAVE THEIR TIME-BARRED CLAIMS.

The R&R correctly concluded that Plaintiffs' claims rely upon conduct dating back more than twenty-five years; that the most generous limitation period for any claim is five years; and that absent some well-pled tolling exception, all claims based upon conduct predating December 20, 2012, are barred by the limitation period (R&R at 54–56). Yet, the R&R essentially kicked the can down the road, pointing to a handful of conclusory allegations to find tolling. *See id.* In doing so, the R&R ignored (i) controlling Sixth Circuit law requiring that Plaintiffs plead specific facts to satisfy any statute of limitations exception, and (ii) Plaintiffs' own allegations, which make clear that no tolling exception is applicable here.

The R&R invoked the fraudulent concealment and continuing violation doctrines, but neither applies. With respect to Plaintiffs' fraudulent concealment theory,¹⁴ the R&R relies entirely on a few conclusory allegations without specific facts of fraudulent concealment by *each* Defendant (R&R at 55). *See Pinney Dock*, 838 F.2d at 1465; *Friedman v. Estate of Presser*, 929 F.2d 1151, 1160 (6th Cir. 1991) (applying rule). Nor does the R&R identify any specific facts showing any due diligence by Plaintiffs to discover the alleged fraud. *See Reid v. Baker*, 499 F. App'x 520, 527 (6th Cir. 2012) (applying rule).

Worse, the R&R fails to recognize that Plaintiffs' very allegations foreclose this theory.

cause dooms all of Plaintiffs' claims, not just the RICO counts. The Sixth Circuit has made clear that because "the RICO statute incorporates general common law principles of proximate causation, remoteness principles are not limited to cases involving the RICO statute." *Perry*, 324 F.3d at 850. Accordingly, it is not necessary to analyze proximate cause for each claim separately, as the result is the same under RICO or common law. *Id.* at 850–51 (dismissing negligence, fraud, unjust enrichment, and state consumer protection act counts on remoteness grounds).

¹⁴ To show fraudulent concealment under federal law, Plaintiffs must allege specific facts, consistent with Rule 9(b), to show "that: (1) the defendant concealed the conduct that constitutes the cause of action; (2) defendant's concealment prevented plaintiff from discovering the cause of action within the limitations period; and (3) until discovery plaintiff exercised due diligence in trying to find out about the cause of action." *Pinney Dock & Transp. Co. v. Penn Cent. Corp.*, 838 F.2d 1445, 1465 (6th Cir. 1988). Fraudulent concealment under Ohio law imposes similar requirements. *See, e.g., Sharp v. Ohio Civil Rights Comm'n*, 2005-Ohio-1119, at ¶ 10 (Ohio Ct. App. 2005).

Plaintiffs allege that FDA's public regulatory actions related to opioid marketing began as early as 2001 (SAC ¶¶ 188–91, 260, 304, 316, 763–64); articles related to opioids and opioid addiction were published as early as 2001 (*id.* ¶¶ 256, 260, 273, 275); Manufacturer Defendants' efforts to market opioids were public and started in the late 1990s (*id.* ¶¶ 7, 159, 173–78); and the effects of opioid crisis were felt in Summit County long before 2013, with Plaintiffs allegedly incurring millions of opioid-related costs prior to 2013 (*id.* ¶¶ 717, 719, 727, 728, 731, 732, 741, 744). Based upon their *own* allegations, Plaintiffs did not act diligently by waiting until 2017 to sue.

The R&R's invocation of the continuing violation doctrine fares no better, as the R&R simply *assumes* the doctrine applies to Plaintiffs' particular claims – without identifying a single decision by any court to support that conclusion.¹⁵ Further, the R&R rests its argument upon general statistics and conclusory allegations about the effects of the opioid crisis – without identifying any well-pled factual allegations to support any of the elements of this doctrine as to each (or any) Defendant. R&R at 55.¹⁶ Indeed, Plaintiffs' claims do not allege “continuing violations” but rather “repetitive discrete violations” – that is, separate alleged misrepresentations or omissions allegedly made by different Defendants at different times to different physicians. At most, Plaintiffs allege the continuing effects of discrete but similar acts, but that is insufficient to trigger tolling. *See Pittman v. Spectrum Health Sys.*, 612 F. App'x 810, 814–15 (6th Cir. 2015). As such, all claims based upon conduct prior to (at least) December 20, 2012, are time-barred.

¹⁵ To the contrary, both the Ohio Supreme Court and the Sixth Circuit have recognized that the continuing violation doctrine has generally been limited to the Title VII context. *Nat'l Parks Conserv. Ass'n v. Tenn. Valley Auth.*, 480 F.3d 410, 416 (6th Cir. 2007); *State ex rel. Nickoli v. Erie MetroParks*, 923 N.E.2d 588, 594 (Ohio 2010).

¹⁶ For the doctrine to apply, a plaintiff must show: “(1) the defendants engage in continuing wrongful conduct; (2) injury to the plaintiff accrues continuously; *and* (3) had the defendants at any time ceased their wrongful conduct, further injury would have been avoided.” *Hensley v. City of Columbus*, 557 F.3d 693, 697 (6th Cir. 2009).

IV. MANUFACTURERS DO NOT HAVE A DUTY TO PLAINTIFFS TO MONITOR OR REPORT SUSPICIOUS ORDERS

The R&R found that Plaintiffs pleaded a viable alternative theory – that the Manufacturers allegedly breached a duty to Plaintiffs to prevent opioid abuse by failing to monitor downstream sales and to report downstream suspicious orders (R&R at 47 (failure to monitor as a RICO predicate act), 76–77 (failure to monitor as a viable negligence claim)). But the R&R is simply incorrect on the law on multiple levels. First, pharmaceutical manufacturers’ duty to monitor and report “suspicious” orders is owed to the *Drug Enforcement Administration* (“DEA”),¹⁷ not Plaintiffs, and the right to enforce any such obligation lies exclusively with the federal government. Plaintiffs cannot circumvent the lack of a private cause of action in the Controlled Substances Act (“CSA”), 21 U.S.C. § 823, or its regulations. *See, e.g., Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 118 (2011); *Myers v. United States*, 17 F.3d 890, 901 (6th Cir. 1994) (“were we to permit them to proceed on the basis of negligence *per se*, we would, in effect, be permitting a private cause of action under the Act”).

In addition, manufacturers sell to wholesale distributors and have no legal duty to monitor, report, or prevent *downstream* diversion of prescription opioids at the pharmacy or physician level, where diversion occurs. *See* 21 C.F.R. § 1301.74(b) (DEA regulations require only that DEA registrants, “design and operate a system to disclose to the registrant suspicious *orders* of controlled substances,” and “inform [DEA] of suspicious *orders* when discovered by the registrant.”) (emphasis added). Tellingly, the R&R does not suggest that manufacturers have an affirmative duty to *monitor* for such “downstream” diversion; it merely opines that a

¹⁷ The relevant DEA regulation provides only that “[t]he registrant shall *inform the Field Division Office of the [DEA]* . . . of suspicious orders when discovered by the registrant.” 21 C.F.R. § 1301.74(b) (emphasis added). And it is solely “the *Administrator* [who] shall use the security requirements set forth [under federal law]” “[i]n order to determine whether a registrant has provided effective controls against diversion.” *Id.* § 1301.71(a) (emphasis added).

manufacturer may have a duty under DEA regulations “to **report**” a suspicious, “downstream” order “whenever one is ‘discovered.’” R&R at 47 (emphasis added). But manufacturers in fact have neither duty. The statute only requires registrants (like manufacturers) to make reports to the DEA for “every sale, delivery, or other disposal *by him*,” 21 U.S.C. § 827(d) (emphasis added), and, as used in the CSA’s implementing regulations, the term “orders” uniformly means orders placed with the registrant itself.¹⁸ Therefore, under the plain text of the statute and its implementing regulations, the Manufacturers’ duty extends only to monitoring and reporting suspicious orders placed **with them by their direct customers** (e.g., pharmaceutical distributors), rather than a duty to monitor every downstream level of the entire opioid market.

It would be legal error to adopt a ruling based on the flawed belief that manufacturers have downstream monitoring and reporting duties outside of direct orders that the law does not impose, and the Court should not do so here. And of course, the existence of a duty (or lack thereof) is a threshold legal question for the Court, and thus should be ruled on at this stage. *Wheeler v. Estes Exp. Lines*, 53 F. Supp. 3d 1032, 1043 (N.D. Ohio 2014) (“‘The threshold question of the existence of a duty is a question of law’ for the court to decide.” (quoting *Barnett v. Beazer Homes Inves., L.L.C.*, 905 N.E.2d 226, 230 (Ohio App. 2008))). The claims against Manufacturers for the failure to monitor or report suspicious orders should be dismissed.

Dated: November 2, 2018

Respectfully submitted,

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¹⁸ See also, e.g., 21 C.F.R. § 1305.27(a)-(b) (requiring purchasers and suppliers to retain records of each electronic order filled for two years); *id.* § 1305.29 (requiring suppliers of Schedule I or II substances to forward a copy of each electronic order filled, or a report of that order, to the DEA within 2 business days).

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CERTIFICATE OF SERVICE

I hereby certify that on November 2, 2018, a copy of the foregoing Manufacturer Defendants' Objections to the Report and Recommendation on Their Joint Motion to Dismiss Plaintiffs' Second Amended Complaint was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

Dated: November 2, 2018

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